

c 1  
a nozzle sleeve moveably mounted at the first end of the barrel from a first position where the tip of the needle is concealed by the nozzle sleeve to a second position where the tip of the needle is exposed, to an activation position, wherein when the nozzle sleeve is initially pressed against an injection site, the nozzle sleeve moves from the first position to the second position, and the tip of the needle penetrates the injection site, and when the sleeve moves from the second position to the activation position, said energization source is activated to move said piston which drives a liquid from the reservoir

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**REMARKS**

Claims 29 and 31-39 remain in this application with Claim 29 having been amended and with Claims 30 and 40-82 having been previously cancelled to expedite the prosecution of this application; Claims 1-28 were also previously cancelled in a Preliminary Amendment filed on July 17, 2000.

The Examiner has rejected Claims 29 and 34-37 under 35 U.S.C. §102(b) as being anticipated by Galli (WO 94/11041). In particular, the Examiner states that:

...Galli discloses a syringe comprising a barrel, needle, energization source 22, actuator, spring retractor 36 biasing the sleeve and nozzle sleeve moveably mounted on the barrel from a first position with needle concealed to second position with needle exposed, to a third activation position where said energization source is activated to move a piston to drive liquid from the reservoir through the needle (pg 11, lines 9-21).

Applicants respectfully disagree for the following reasons.

Galli fails to disclose a nozzle sleeve that is moveably mounted at the first end of the barrel. In particular, if the Examiner takes the position that the slider 5 of the Galli device is similar to the "nozzle sleeve" of the present invention and the cylindrical body 1 of the Galli device is similar to the "barrel" of the present invention, then the slider

5 of Galli is not moveably mounted at the first end of the barrel because, if anything, the slider 5 is moveably mounted at the cylindrical body's upper end; this would correspond to the second end, not the first end, of the barrel of the present invention. Thus, Applicant respectfully submits that Claim 29 is patentable over Galli and respectfully requests that the §102(b) rejection be withdrawn.

Claim 34 is dependent upon Claim 29 and is patentable for the same reasons.

Claim 35 is dependent upon Claim 29 and is patentable for the same reasons. Furthermore, because the Galli device does not include a nozzle sleeve moveably mounted at the first end of the barrel, the Galli device also does not comprise a flexible retractor located between the needle 10 and the slider 5. Thus, for all of these reasons, Claim 35 is patentable over Galli and respectfully requests that the §102(b) rejection be withdrawn.

Claim 36 is dependent upon Claim 35 and is patentable for the same reasons.

Claim 37 is dependent upon Claim 29 and is patentable for the same reasons. Furthermore, the slider of Galli does not move axially and rotationally relative to the barrel between the first position and the second position. Thus, for all of these reasons, Claim 37 is patentable over Galli and respectfully requests that the §102(b) rejection be withdrawn.

degree  
of  
rotation  
?

The Examiner has rejected Claims 31-32 and 39 under 35 U.S.C. §103(a) as:

...being unpatentable over GALLI as applied to claim 29 above, and further in view of RADCLIFFE (U.S. Patent No. 3,867,938). Galli discloses the claimed invention except for the use of a gas generator

to provide the force to expel medication from the syringe. Radcliffe teaches the use of a solid solution of citric acid and sodium bicarbonate in separate compartments that combine to generate gas for propelling medication out of the syringe. It would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of Radcliffe in the syringe of Galli in order to provide an alternative means of force for driving medication out of the syringe. Re claim 39 the use of needle covers for safety reasons is notoriously well known in the art.

Applicants respectfully disagree for the following reasons.

Claim 31 is dependent upon Claim 29 and is patentable for the same reasons. Furthermore, one skilled in the art would not combine Galli with Radcliffe for a number of reasons. The Galli device uses a specialized structure for releasing a spring 22 when a detent ring 19 expands; this spring 22 is axially-aligned to drive a syringe piston 23 downward through the needle 10. In contrast, the gas generator of Radcliffe is directed to a hygienic syringe for injecting a jet of fluid (comprising a medicament chemical) into a body area (e.g., vagina, anal cavity, etc.) of a patient through a tubing and nozzle. As a result, the gas generation is not used for driving a piston; rather, it is used for directly driving a fluid through a conduit (15/18) and into a body cavity. Furthermore, the gas generator of Radcliffe is not self-contained, i.e., it requires the user to insert gas-creating pills into respective chambers and then to fill a reservoir with a liquid (e.g., water) along with the medicament chemical before use<sup>1</sup>. This type of user intervention, using the Galli device, could comprise the effect of the injection if not filled properly; it also defeats a key feature of the automatic syringe of the present invention which is to provide the user with a safe and easy to use injection device. In addition, the only suggestion to combine Galli with Radcliffe is by comparing those two references to the device of the present

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<sup>1</sup>U.S. Patent No. 3,867,938 (Radcliffe), col. 4, lines 53-66.

application. In light of the §103(a) rejection, Applicants remind the Examiner that the mere fact that the references cited may be modified or even combinable does not allow the PTO to meet its burden absent a suggestion in the cited art of the desirability of the modification or combination. Moreover, the PTO may not "use the claimed invention as an instruction manual or 'template' to piece together the teachings of the prior art so that the claimed invention is rendered obvious." In re Fritch, 23 U.S.P.Q.2d 1780 (Fed. Cir. 1992).

Thus, for all of these reasons, Applicants respectfully submit that Claim 31 is patentable over the art of record and respectfully submit that the §103(a) rejection be withdrawn.

Claim 32 is dependent upon Claim 31 and is patentable for the same reasons. Furthermore, as specified in Claim 32, the sodium bicarbonate and the citric acid are pre-stored in the syringe as solutions. In contrast, the Radcliffe generator requires the user to open the device, insert the pills and fill the device with a liquid. Thus, for all of the reasons, Applicants respectfully submit that Claim 32 is patentable over the art of record and respectfully submit that the §103(a) rejection be withdrawn.

Claim 39 is dependent upon Claim 29 and is patentable for the same reasons.

Attached hereto is a marked-up version of the changes made to the claims by the current amendment. The attached page is captioned **"Version with markings to show changes made."**

In view of the foregoing amendments and remarks, it is respectfully submitted that Claims 29 and 31-39 now appearing in this application are allowable and such favorable action is respectfully requested. The Examiner is encouraged to contact the

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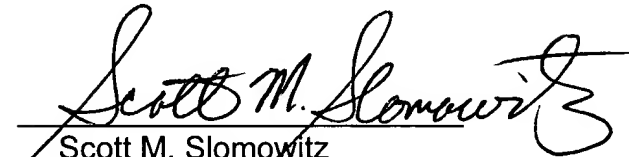
undersigned by telephone if it is believed that further discussion may lead to an early allowance of the claims.

Respectfully submitted,

CAESAR, RIVISE, BERNSTEIN,  
COHEN & POKOTILOW, LTD.

May 7, 2003

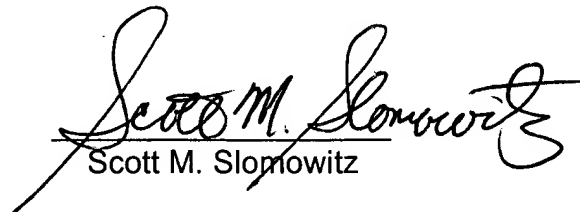
By



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**CERTIFICATE OF MAILING**

I hereby certify that the foregoing AMENDMENT re Application Serial No. 09/617,340 is being deposited with the United States Postal services as first class mail, postage prepaid, in an envelope addressed to: Commissioner of Patents, Mail Stop RCE, Box 1450, Alexandria, VA 22313-1450 on this 7<sup>th</sup> day of May, 2003.



Scott M. Slomowitz

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**Version with Markings to Show Changes Made**

**IN THE CLAIMS:**

Please amend Claim 29 as follows:

On line 7, replace the word "on" with - -at- -.